

OLLERENSHAW et al -- Serial No.: 09/769,769

48. (New) The tissue graft according to claim 14
wherein said tissue graft is cryopreserved.

49. (New) The tissue graft according to claim 14
wherein said starting tissue is obtained from a bovine or
porcine ureter.

REMARKS

Reconsideration of this application and entry of the
foregoing amendments are respectfully requested.

Claim 14 has been revised to define the invention with
additional clarity. Claims 1-13 and 15-46 have been
cancelled and new claims 47-49 have been added. Support
for recitation in claim 14 of decellularization with water
or an aqueous hypotonic buffer can be found at page 4 of
the application, second full paragraph. Support for the
new claims can be found throughout the application,
including in original claims 9 and 13 and in the Examples.
That the claims have been amended/cancelled should not be
taken as an indication that Applicants agree with any
position taken by the Examiner. Rather, the revisions are
made merely to advance prosecution and Applicants reserve
the right to pursue any deleted subject matter in a
continuation application.

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Claims 14, 38 and 39 stand objected to under 37 CFR 1.75(c). Withdrawal of the objection is in order in view of the above-noted claim revisions.

Claims 14, 38 and 39 stand rejected under 35 USC 102(b) as anticipated by Bruchman et al. The rejection is traversed.

Claim 14 is drawn to a tissue graft product from an ureter that is subjected to decellularization and nuclease treatment. The Examiner contends that column 1, lines 19-33, of Bruchman et al teaches such a tissue graft. The only reference to a ureter seen in the cited portion reads:

Attempts have also been made to replace arteries with tissues of nonvascular origin, including autologous or xenogeneic fibrous tissue tubes, bovine ureter, and grafts made from small bowel and pericardium. However, like the above grafts from vascular sources, these nonvascular biological grafts have provided only very limited success.

Nothing is seen in the foregoing that would have been suggestive of a tissue graft produced from a ureter that has been decellularized and nuclease treated, as required by the instant claims. Clarification of the basis for the rejection or withdrawal of same is thus requested.

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Claims 14, 38 and 39 stand rejected under 35 USC 102(b) as anticipated by Knapp et al. The rejection is traversed.

In rejecting the claims as anticipated, the Examiner refers to column 4, lines 48-56, of Knapp et al. This section makes reference to the use of submucosal tissue as a tissue graft for replacing/reconstructing damaged or diseased urothelial tissue. In column 1 of Knapp et al, it is stated that submucosal tissue can be obtained from various sources,

including particularly intestinal tissue harvested from animals raised for meat production

Nothing is seen in the referenced section of Knapp et al of the presently claimed tissue graft which, as indicated above, has been decellularized and nuclease treated. Accordingly, reconsideration is requested.

Claims 14, 38 and 39 stand rejected under 35 USC 102(e) as anticipated by Tanagho et al. The rejection is traversed.

In rejecting the claims over Tanagho et al, the Examiner directs attention to column 2, lines 16-22. This portion of the citation makes reference to an acellular matrix graft isolated from, for example, smooth muscle tissue such as ureter.

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Tanagho et al refers throughout to the use of chemical and enzyme agents to release cellular components (see, for example, column 2, lines 33-35, and Example 1). This is in marked contrast to the present invention wherein lysis is effected using an osmotic effect.

Applicants have found with other tissues that the claimed approach of effecting decellularization results in a product that is less antigenic than the product obtained using chemical poisoning, as taught by the citation. This reduction in antigenicity is clearly advantageous.

In view of the above, reconsideration is requested.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "Version With Markings To Show Changes Made."

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This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADEIN THE CLAIMS:

14. (Amended) A tissue graft [obtainable] produced by a [the] method [according to claim 1] comprising the steps of:

- i) washing a starting tissue obtained from a human or animal ureter with a bioburden reducing agent so that said starting tissue is disinfected,
- ii) decellularizing the disinfected tissue resulting from step (i) with water or an aqueous hypotonic buffer that lyses cells of said disinfected tissue so that a tissue matrix is formed, and
- iii) contacting said tissue matrix resulting from step (ii) with a nuclease so that nucleic acid associated with said tissue matrix is degraded, and
- iv) washing said tissue matrix resulting from (iii) so that cellular or extracellular debris is removed and said tissue graft is produced.

47. (Amended) The [method] tissue graft according to claim [1] 14 wherein said method further [comprising] comprises, after step (iv), sterilizing said tissue matrix.

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48. (Amended) The [method] tissue graft according to
claim [2] 14 wherein said tissue graft is cryopreserved
[further comprising, after step (iv), cryopreserving said
tissue matrix].